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Summary of Safety and Effectiveness
Smith & Nephew, Inc. VLP FOOT Plating, Screw System and Accessories

JUN - 4 2009

Contact Person and Address
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Orthopaedic Division
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Memphis, Tennessee 38116
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Date of Summary: March 11, 2009

Name of Device: Smith & Nephew, Inc. VLP FOOT Plating, Screw System and Accessories
Common Name: Screws, Plates, and K-Wires
Device Classification Name and Reference: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II; 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories – Class II
Panel Code: Orthopaedics/87 HWC, HRS, HTY

Device Description
Subject of this Traditional 510(k) premarket notification is Smith & Nephew, Inc. VLP FOOT Plating, Screw System and Accessories. The system is comprised of a variety of Cannulated Screws, Headless Cannulated Screws, QFX Screws, K-Wires, Cortex Screws, Locking Cortex Screws, Fully and Partially Threaded Osteopenia Screws, Locking Osteopenia Screws and a variety of VLP FOOT plates.

Mechanical Testing Data
A review of the mechanical testing data indicates that the implant components of the VLP FOOT Plating, Screws and Accessories are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Intended Use
The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for the treatment of fracture fixation, reconstruction or arthrodeses of small bones, including those in the forefoot, midfoot and hindfoot.
The Smith & Nephew 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws are intended for fixation of intraarticular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodeses of small joints; bunionectomies and osteotomies; scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.
The Smith & Nephew 2.0mm QFX Screw is indicated for osteotomies of the lesser metatarsals, such as Weil osteotomies. Osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.
Pins and wires are indicated for pelvic, small and long bone fracture fixation.

Substantial Equivalence Information
The substantial equivalence of the VLP FOOT Plating, Screws System and Accessories is based on its similarities in indications for use, design features, operational principles, and material composition to the predicate devices listed in the table below.

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Description	510(k)	Clearance Date
Smith & Nephew 6.5mm and 8.0mm Cannulated Screws	K060736	4/18/06
Synthes 2..4mm Cannulated Screw	K012945	12/03/2001
Synthes 3.0mm Cannulated Screw	K962823	10/01/96
Synthes 3.0mm Headless Compression Screw	K050636	4/21/05
DePuy FRS Screw	K062352	10/19/2006
Smith & Nephew K-Wires	Pre-amendment device	
PERI-LOC Periarticular Locked Plating System VLP Plates/Screws	K071563	8/8/2007
Smith & Nephew Locking Bone Plate System Peri-articular Plates	K033669	12/10/2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Jahanvi Agnihotri
1450 East Brooks Road
Memphis, Tennessee 38116

JUN - 4 2009

Re: K090675
Trade/Device Name: Smith & Nephew VLP FOOT Plating, Screw System and Accessories
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC, HTY
Dated: May 13, 2009
Received: May 14, 2009

Dear Ms. Agnihotri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K090675

Device Name: Smith & Nephew, Inc. VLP FOOT Plating, Screw System and Accessories
Indications for Use:

The VLP FOOT Plating, Screw System and Accessories is indicated for the following:

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for the treatment of fracture fixation, reconstruction or arthrodeses of small bones, including those in the forefoot, midfoot and hindfoot.
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Pins and wires are indicated for pelvic, small and long bone fracture fixation.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090675